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EXAMINER

ZHENG, LI

ART UNIT

PAPER NUMBER

1638

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,658	<b>Applicant(s)</b> GELVIN ET AL.	
	<b>Examiner</b> Li Zheng	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 15, 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-14 and 16-21 is/are rejected.
- 7) ☒ Claim(s) 1-5, 9-14 and 16-21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2192004</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group V, claims 16-21, in the reply filed on 03/09/2006 is acknowledged. However, during the examination, it was determined that it would not be an undue burden to search and examine the invention groups I, III and V together. Groups I, III and V are therefore rejoined. The examiner, however, maintains the restriction requirement for all other groups.

The requirement is therefore made FINAL.

### ***Specification***

2. The disclosure is objected to because of the following informalities: the recitation, "bit", in [00075], line 4 appears to be a typographical error.

Appropriate correction is required.

### ***Claim Objections***

3. Claims 1-5, 9-14 and 16-21 are objected to because of the following informalities: the claims should not be numbered as [C#]. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1638

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5, 9-14 and 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 9 and 16: the last step is inconsistent with the preamble. The last step results in transgenic plant expressing the DNA of interest, but does not indicate whether stable transformation occurs or that the efficiency is increased. It is also unclear what is the method being compared to for determining that the stable transformation efficiency is increased.

In claim 21: the recitation, "embryo", renders the claim indefinite. The embryo is not a host plant.

5. Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: introduction of a polynucleotide sequence encoding a plant histone protein into the host plant. The specification teaches that such a polynucleotide must be introduced into and expressed in the host plant.

Art Unit: 1638

Claim 16, however, does not indicate that the polynucleotide sequence encoding H2A is transgenic.

6. Claims 16-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for increasing *Agrobacterium* mediated transformation efficiency using host plant expressing H2A protein and L-cysteine as antioxidant in cocultivation medium, does not reasonably provide enablement for a method for increasing *Agrobacterium* mediated transformation efficiency using host plant expressing H2A protein and any other antioxidant in cocultivation medium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Claim 16 is broadly drawn to a method for increasing *Agrobacterium* transformation efficiency in any monocot, comprising: a) selecting a host plant expressing a plant histone H2A protein; b) infecting the host plant with *Agrobacterium*; c) providing at least one antioxidant in a cocultivation medium; d) selecting transgenic cells.

The specification teaches that when maize embryo expressing heterologous RAT5 gene of *Arabidopsis* encoding histone H2A protein, is used in *Agrobacterium* transformation in presence of L-cysteine in cocultivation medium, the overall transformation efficiency is increased (see example 2 and table 2 on page 31).

The specification only enables using L-cysteine as antioxidant agent. Enriquez-Obregon et al. (1999, *Plant Cell, Tissue and Organ Culture* 59:159-168) teach the effect of two compounds, ascorbic acid and cysteine, on the viability of rice stem sections and on the interaction with *Agrobacterium*, and show that the concentration that favors cell viability may not favor the development of calli. The cysteine concentration determined by Enriquez-Obregon et al. for rice transformation (paragraph bridging pages 163-164) is quite different from the one determined by instant invention. Enriquez-Obregon et al. teach that even at 80 mg/l of cysteine, the calli obtained are not suitable for regeneration. Therefore, undue experimentation would have been required for a person skilled in the art to determine the optimal concentration not only for different antioxidants but also for different plant hosts and tissues used for transformation. Finally, step (a) in instant claim 16 encompasses a wild type plant expressing endogenous H2A protein, which is clearly not enabled. The specification teaches that the host plant transgenically expresses the Arabidopsis RAT5 gene. Transgenic expression of this gene is essential to the method, but is missing from the claim. See MPEP 2172.01 and 2164.08 (c). Given the breadth of the claims, lack of guidance on antioxidant and unpredictability of optimal concentration of antioxidant used for transformation, undue experimentation would have been required by one skilled in the art to practice the full scope of the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 14, 16, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enriquez-Obregon et al. in view of Mysore et al. (2000, PNAS 97:948-953).

The instant claim 16 is drawn to a method for increasing *Agrobacterium* transformation efficiency in monocot comprising: a) selecting a host plant expressing a plant histone H2A protein; b) infecting the host plant with *Agrobacterium*; c) providing at least one antioxidant in a cocultivation medium; d) selecting transgenic cells.

Enriquez-Obregon et al. teach that GUS gene is transformed into rice by Agrobacterium-mediated transformation and effect of antioxidant L-cysteine in coculturing medium is evaluated. Cocultivation was for 3 days (abstract also paragraph bridging Pages 163-164).

Enriquez-Obregon et al. do not teach step (a) of claim 16, which is selecting a host plant expressing a transgenic polynucleotide sequence encoding a plant H2A protein.

Mysore et al. teach that overexpression of RAT5 gene encoding H2A histone protein could increase the Agrobacterium transformation efficiency in plant (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method by Enriquez-Obregon et al. by transgenically overexpressing the RAT5 gene of Mysore et al., thus resulting in the practice of the instantly claimed invention. One would have been motivated to do so given the teaching of Mysore et al. that transgenic overexpression of H2A could increase the susceptibility of a plant to Agrobacterium transformation (lines4-6 on right column of page 953).

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Enriquez-Obregon et al and Mysore et al as applied to claim16 above, and further in view of Yu et al (US Patent 6215051 B1).

The instant claim 21 is drawn to a method for increasing Agrobacterium transformation efficiency in monocot comprising: a) selecting an embryo expressing a



Art Unit: 1638

plant histone H2A protein; b) infecting the embryo with *Agrobacterium*; c) providing at least one antioxidant in a cocultivation medium; d) selecting transgenic cells.

Enriquez-Obregon et al. and Mysore et al. teach a method for increasing *Agrobacterium*-mediated transformation efficiency as discussed above.

Enriquez-Obregon et al and Mysore et al do not teach transforming embryo.

Yu et al teach that immature rice embryo is used for *Agrobacterium*-mediated transformation (abstract).

It would have been obvious for a person with ordinary skill in the art to modify the method taught by Enriquez-Obregon et al and Mysore et al to use immature embryo for *Agrobacterium*-mediated transformation with a reasonable expectation of success. One would have been motivated to do so given the teaching of Yu et al that immature embryos, as young tissues contain relatively fewer inhibitors or more virulence inducers, and therefore can be used for transformation of rice (paragraph bridging columns 4 and 5).

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Enriquez-Obregon et al. and Mysore et al. as applied to claim 16 above, and further in view of Narasimhulu et al. (1996, *The Plant Cell* 8:873-886).

The instant claim 17 is drawn to a method for increasing *Agrobacterium* transformation efficiency in monocot comprising: a) selecting a maize plant expressing a plant histone H2A protein; b) infecting the maize plant with *Agrobacterium*; c) providing at least one antioxidant in a cocultivation medium; d) selecting transgenic cells.

Art Unit: 1638

Enriquez-Obregon et al. and Mysore et al. teach a method for increasing Agrobacterium-mediated transformation efficiency as discussed above.

Enriquez-Obregon et al. and Mysore et al. do not teach transform maize plant.

Narasimhulu et al. teach that Gus gene is used to study T-DNA integration into maize genome (abstract).

It would have been obvious for a person with ordinary skill in the art to modify the method taught by Enriquez-Obregon et al and Mysore et al to use maize for Agrobacterium-mediated transformation with reasonable expectation of success. One would have been motivated to do so given the teaching of Narasimhulu et al that the block to maize transformation involves T-DNA integration (paragraph bridging left and right Columns of page 882) and the teaching of Mysore et al. that RAT5 is involved in T-DNA integration and overexpression of RAT5 increase the transformation efficiency. One would also obviously have been motivated to increase transformation efficiency of maize given its worldwide agronomic importance.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-5, 9, 12 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-3 of U.S. Patent No.

6,696,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of U.S. Patent No. 6,696,622 is drawn to a method for increasing the Agrobacterium transformation efficiency using a host plant expressing transgenically any plant histone H2A and therefore anticipate claims 1 and 9. Claim 3 of U.S. Patent No. 6,696,622 requires the H2A to be the Arabidopsis RAT5, and the claim therefore anticipates instant claims 2, 3, 5, 12 and 13. The histone H2A encoded by Arabidopsis RAT5 gene is H2A-1. Page 21 of the instant specification indicates that the H2A of Fig. 5 is H2A-1 (paragraph [00077]). The brief description of Fig. 5 on Page 9 indicates that the figure shows a Northern blot of H2A expression. H2A is Arabidopsis RAT5. It is obvious that the efficiency of Agrobacterium-mediated transformation would be measured by the number o tumors produced.

11. Claims 10-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,696,622 in view of Goldman et al (U.S. Patent No. 5187073).

Claim 3 of U.S. Patent No. 6,696,622 is drawn to a method for increasing the Agrobacterium transformation efficiency using a host plant expressing transgenically RAT5 of Arabidopsis encoding a H2A histone.

Claim 3 of U.S. Patent No. 6,696,622 does not specifically teach monocot or maize as host plant, but does broadly encompass all plant species.

Goldman et al. teach a method of transforming maize using Agrobacterium (abstract).

It would have been obvious for a person with ordinary skill in the art to practice the method taught by claim 3 of U.S. Patent No. 6,696,622 in maize or monocot transformation method of Goldman et al with reasonable expectation of success. One would obviously have been motivated to increase transformation efficiency of maize or monocot given its worldwide agronomic importance.

12. Claims 14, 16-18 and 20-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,696,622 in view of Goldman et al, Yu et al., and Enriquez-Obregon et al.

Claim 3 of U.S. Patent No. 6,696,622 is drawn to a method for increasing the Agrobacterium transformation efficiency using a host plant expressing transgenically RAT5 of Arabidopsis encoding a H2A histone.

Claim 3 of U.S. Patent No. 6,696,622 does not anticipated monocot, maize or embryo of monocot as host cell. Claim 3 also does not teach using at least one

antioxidant such as L-cysteine in cocultivation medium or infecting of plant host in the cocultivation medium for about 3 day.

Enriquez-Obregon et al. teach that GUS gene is transformed into rice by Agrobacterium-mediated transformation and effect of antioxidant L-cysteine in coculturing medium is evaluated. Cocultivation was for 3 days (abstract also paragraph bridging Pages 163-164).

Yu et al teach that immature rice embryo is used for Agrobacterium-mediated transformation (abstract).

Goldman et al. teach a method of transforming maize using Agrobacterium (abstract).

It would have been obvious for a person with ordinary skill in the art to modify the claimed method of U.S. Patent No. 6,696,622 to use any monocot including maize for Agrobacterium-mediated transformation as taught by Goldman et al. by using L-cysteine as antioxidant in a cocultivation medium as taught by Enriquez-Obregon et al. with reasonable expectation of success. One would have been motivated to do so given the teaching of Enriquez-Obregon et al. that pretreatment with antinecrotic compounds could enhance cell viability and minimize the oxidative bursts during the plant-microorganism interaction as well as the fact that increasing transformation efficiency of maize or monocot is highly desirable because of its worldwide agronomic importance. It would have been obvious to transform plant embryo, given the teaching of Yu et al that immature embryos contain relatively few inhibitors or more virulence inducers (paragraph bridging columns 4 and 5).

13. Claims 1-5, 9, 12 and 13 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 10-14 of copending Application No. 10/098,161. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 12 of U.S. Patent Application No. 10/098,161 is drawn to a method for increasing the Agrobacterium transformation efficiency using a host plant having increased histone level by expressing transgenically RAT5 of Arabidopsis encoding H2A histone. Claim 13 of Application No. 10/098,161 requires transformation efficiency to be measured by the number of tumors, which is obvious to a person with ordinary skill in the art. Therefore the claims of Application No. 10/098,161 anticipate instant claims 1-5, 9, 12 and 13.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 10-11 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-2 and 10-14 of copending Application No. 10/098,161 in view of Goldman et al.

Claim 12 of U.S. Patent Application No. 10/098,161 is drawn to a method for increasing the Agrobacterium transformation efficiency using a host plant expressing transgenically RAT5 of Arabidopsis encoding a H2A histone.

Claim 12 of U.S. Patent Application No. 10/098,161 does not anticipate monocot or maize as plant.

Goldman et al. teach a method of transforming maize using Agrobacterium (abstract).

It would have been obvious for a person with ordinary skill in the art to practice the method taught by 12 of U.S. Patent No. 10/098,161 in maize or monocot transformation method of Goldman et al with reasonable expectation of success. One would obviously have been motivated to increase transformation efficiency of maize or monocot given its worldwide agronomic importance.

This is a provisional obviousness-type double patenting rejection.

15. Claims 14, 16-18 and 20-21 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 10-14 of copending Application No. 10/098,161 in view of Goldman et al, Yu et al. and Enriquez-Obregon et al.

Claim 12 of U.S. Patent No. 10/098,161 is drawn to a method for increasing the Agrobacterium transformation efficiency using a host plant expressing transgenically RAT5 of Arabidopsis encoding a H2A histone.

Claim 12 of U.S. Patent No. 10/098,161 does not anticipated monocot, maize or embryo of monocot as host cell. Claim 3 also does not teach using at least one antioxidant such as L-cysteine in cocultivation medium or infecting of plant host in the cocultivation medium for about 3 day.

Enriquez-Obregon et al. teach that GUS gene is transformed into rice by Agrobacterium-mediated transformation and effect of antioxidant L-cysteine in

Art Unit: 1638

coculturing medium is evaluated. Cocultivation was for 3 days (abstract also paragraph bridging Pages 163-164).

Yu et al teach that immature rice embryo is used for Agrobacterium-mediated transformation (abstract).

Goldman et al. teach a method of transforming maize using Agrobacterium (abstract).

It would have been obvious for a person with ordinary skill in the art to modify the claimed method of U.S. Patent No. 10/098,161 to use any monocot including maize for Agrobacterium-mediated transformation as taught by Goldman et al. by using L-cysteine as antioxidant in a cocultivation medium as taught by Enriquez-Obregon et al. with reasonable expectation of success. One would have been motivated to do so given the teaching of Enriquez-Obregon et al. that pretreatment with antinecrotic compounds could enhance cell viability and minimize the oxidative bursts during the plant-microorganism interaction as well as the fact that increasing transformation efficiency of maize or monocot is highly desirable because of its worldwide agronomic importance. It would have been obvious to transform plant embryo, given the teaching of Yu et al that immature embryos contain relatively few inhibitors or more virulence inducers (paragraph bridging columns 4 and 5).

This is a provisional obviousness-type double patenting rejection.



***Conclusion***

Claims 1-5, 9-14 and 16-21 are rejected.

No claim is allowed at this point.


The claims 14 and 16-21 are not given the priority date as the filing date of parent applications since the claims as a whole invention are not fully supported by parent applications. Particularly, adding L-cysteine in cocultivation medium or the step c of claims 16-21, which is the addition of antioxidant in cocultivation medium, is not taught in previous application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**ASHWIN D. MENTA, PH.D.**  
**PRIMARY EXAMINER**